

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in July 2013.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-544

Trade Name: Zilmax® plus Rumensin® plus Tylovet® 100 plus MGA®
Pioneer: Zilmax® plus Rumensin® plus Tylan® plus MGA®
Ingredients: Zilpaterol hydrochloride plus monensin USP plus tylosin phosphate plus melengestrol acetate
Sponsor: Huvepharma AD
Approval Date: May 24, 2013
Status: OTC
Route: Oral, in feed
Species: Cattle, heifers fed in confinement for slaughter
Drug Form: Type A medicated articles
Concentration: Zilpaterol hydrochloride – 21.77 g/lb
Monensin USP – 80 g/lb
Tylosin phosphate – 40 and 100 g/lb
Melengestrol acetate – 100 and 200 mg/lb (dry) and 500 mg/lb (liquid)
Indications: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* and reduction of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*, and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 20 to 40 days on feed.

21 CFR 558.665

78 FR 42006-42008

NADA Number: 141-345

Trade Name: apoquel®
Ingredients: Oclacitinib
Sponsor: Zoetis, Inc.
Approval Date: May 14, 2013
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Tablet
Concentration: 3.6, 5.4, or 16 mg of oclacitinib as oclacitinib maleate per tablet
Indications: Control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.
Exclusivity: 5 years

21 CFR 520.1604

78 FR 42006-42008

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-279

Trade Name: Nicarb® 25% plus BMD®
Ingredients: Nicarbazine and bacitracin methylene disalicylate
Sponsor: Zoetis, Inc.
Approval Date: April 12, 2013

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The following corrections or additions to the list were published in the Federal Register in July 2013.

This supplement revises nicarbazin dosage to a range consistent with the dosage approved for use in combination feeds.

21 CFR 558.366

78 FR 42006-42008

Sponsor Change

NADA Number: 141-337

Previous: Nexcyon Pharmaceuticals, Inc.

New Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.

Drug Labeler Code: 000986

21 CFR 524.916

78 FR 44432-44433

NADA Numbers: 099-667, 110-399

Previous: Alstoe, Ltd., Animal Health

New Sponsor: Sogeval S.A.

Drug Labeler Code: 059120

21 CFR 522.1182, 510.600

78 FR 44432-44433